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| 47231 | 7590 | 08/02/2007 | | |
| PATRICK R. SCANLON | | | EXAMINER | |
| PRETI FLAHERTY BELIVEAU & PACHIOS LLP | | | KISHORE, GOLLAMUDI S | |
| ONE CITY CENTER | | | | |
| PORTLAND, ME 04112-9546 | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,539

Applicant(s)

ECHOLS ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2-27-04 ; 3-31-06
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group I in the reply filed on 5-25-07 is acknowledged. The traversal is on the ground(s) that was as argued on page 2 of the response. This is not found persuasive because of the following reasons. Applicant argues that with respect to inventions I and III there is no indication how the proposed method of forming the composition would be materially different from the method claimed in 15-18. Applicant appears to misunderstand the reasons. The restriction is proper if the composition is to shown to be made by a different method; this implies the same composition and not materially different composition as argued by applicant. With respect to applicant's argument that the examiner has not provided any rationale as to why invention II is distinct from invention III, the examiner points out that the process in III does not make the composition in II which has three separate layers. With respect to III and IV, the examiner once again points out that III is drawn to a method of preparation and IV is drawn to a method of use. With respect to I and II, the examiner points out that II is a three-layer preparation whereas I is a single composition.

The requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 1-7.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1615

3. Claims 1-7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between the hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol in claim 1 is unclear.

The use of trademark in the claims is improper. The examiner suggests reciting the specific components in Amisol R.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (6,132,751) in combination with Guy (5,540,930) and Holly (4,883,658).

Suzuki discloses emulsion compositions for eyes drops. The compositions contain water, phospholipids such as lecithin, polyvinyl alcohol, polyvinyl pyrrolidone, isotonicizing agents such as glycerol and solvents such as ethanol (col. 4, line 17-26, col. 6, lines 54-67, col. 7, lines 33-44, Examples).

Guy discloses eye formulations. The formulations contain water, PVP, PVA, glycerol and Tween 80 (col. 3, line 10 through col. 4, line 19).

Holly while disclosing ophthalmic solutions for treatment of dry-eye syndrome teaches that the combination of an aqueous solution of a partially hydrolyzed polyvinyl

Art Unit: 1615

acetate and polyvinyl alcohol is synergistic. The compositions further contain polyvinylpyrrolidone (abstract, col. 3, line 51 through col. 5, line 27, examples and claims).

To include a surfactant such as Tween 80 in the formulations of Suzuki would have been obvious to one of ordinary skill in the art since Guy who teaches ophthalmic formulations teaches the use of a non-ionic surfactant such as Tween 80. The addition of polyvinyl acetate in Suzuki would have been obvious to one of ordinary skill in the art since the combination of polyvinyl acetate and polyvinyl alcohol is synergistic as taught by Holly.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (6,132,751) in combination with Guy (5,540,930) and Holly (4,883,658) as set forth above, further in view of applicant's statements of prior art.

The teachings of Suzuki, Guy and Holly have been discussed above. Suzuki in particular teaches the use of lecithin, glycerol, ethanol and water.

Applicant on page 6 of the specification state that the combination of lecithin, ethanol, glycerol, polysorbate 80 is readily available in the market under the trade name Amisol. One of ordinary skill in the art would be motivated to use Amisol since it already contains premixed lecithin, ethanol, glycerol and polysorbate 80, the individual components taught by Suzuki and Guy in particular.


The reference of Cronin (2,897,120), which discloses formulations for ophthalmic use containing polyvinyl pyrrolidone, polyvinyl alcohol, and lecithin, is cited of interest.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK